CUSTOMER NO.: 31013 DOCKET NO.: 100391-02030

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Mark Martin

Serial No.: 10/039,471

Filing Date: October 19, 2001

For: METHODS AND COMPOSITION FOR MODIFYING BIOLOGICALLY ACTIVE TARGET MOLECULES

Commissioner for Patents
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Date: June 17, 2004

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RESTRICTION REQUIREMENT

Sir:

Applicants elect claims 1-16 and 27-33, Group I, with traverse, for further prosecution in this application.

Applicants respectfully traverse the requirement for the following reasons:

Applicants urge the restriction is improper since it restricts into separate groups claims that are not independent and distinct. More specifically, the restriction restricts claimed subject matter relating to method species falling within the scope of generic claim 1. Applicants submit that the Examiner is apparently confusing the Restriction requirement under 37 CFR 1.121 with the Election of Species requirement of 37 CFR 1.141 since the Examiner is improperly restricting species within generic claims. For example, Groups I-IX are restricted even though each contains the same set of method

claims 1-16 and 27-33. Applicants submit that such a restriction requirement dividing species within generic claims is improper.

For example, the present claims include generic claim 1 that covers all of the species in Groups I-IX and XVIII, which groups are restricted by the Examiner. The claims in the restricted groups merely identify species methods within generic method claim 1 which recites:

> 1. A method of modifying a biologically active target molecule comprising contacting said target molecule with a catalyst capable of chemically modifying said target molecule, said contacting being effected under conditions sufficient for said catalyst to modify said target molecule.

Groups II-IX, for example, relate to different species of the method of claim 1 by defining the type of chemical modification occurring (e.g., by linking, by modulating the activity, by deactivating, etc.). Thus, to answer the Examiner's question in the last paragraph of the Office Action, the claims of groups II-IX merely define specific preferred steps and the preferred modifications of the target molecules in the method of the generic claim 1 and the methods of claims 1-16 and 27-33 (Groups I-IX) can be used to modify all of the target molecules of Groups X-XIII using catalytic antibodies of claims 17-26 (Groups X-XIII). Moreover, the methods of Groups XIV-XVII all relate to the use of a catalytic antibody catalyst to chemically modify a particular target for the treatment of a particular disease and thus also fall within the scope of generic claim 1.

Applicants urge that it is improper to restrict the species falling within generic claim 1. Under 37 CFR 1.141, a generic claim, if allowed, may link a reasonable number of species embraced thereby. (See, MPEP 809.02) Even if the examiner rejects the generic claims, and even if the applicant cancels the same and admits that the genus is unpatentable, where there is a relationship disclosed between

species, such disclosed relation must be discussed and reasons advanced leading to the conclusion that the disclosed relation does not prevent restriction, in order to establish the propriety of restriction. (See, MPEP 808.01(a)) The Examiner has not provided a required discussion and did not advance reasons supporting the proposed restriction.

The MPEP clearly states:

> For purposes of the initial requirement, a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation of separate classification, or separate status in the art, or a different field of search as defined in MPEP § 808.02.

[MPEP 803]

Thus, the Examiner has failed to establish a *prima facie* showing for the following reasons:

1. Groups I-IX and XVIII suggested by the Examiner belong to a single classification class 435 and subclass 41+.

2. Contrary to the Examiner's assertion, the methods are closely related, as specific preferred embodiments of the generic claim 1.

3. Each of claims 1-16, 27-33 and 42-45 relate to methods falling within the scope of generic claim 1.

4. Only one field of search is required due to the close relation between the methods.

Therefore, Applicants submit that the restriction requirement is improper and should be withdrawn. The rejoinder of the Groups II-IX and XVIII with Group I, which represents claims 1-16, 27-33 and 42-45, is respectfully requested.

In addition, the claims in groups XIV-XVII, which belong to a single classification class 424 and subclass 94.1, merely relate to methods of modifying preferred target molecules using

modification method of claim 1 to treat disease conditions associated with these target molecules. Fundamentally they are the species methods of the generic claim 1 in Group I. Thus, the rejoinder of the Groups XIV-XVII with Group I is also respectfully requested.

Moreover, Groups X-XIII, claims 17-26, merely relate to catalytic antibodies for use in the method of method claim 1.

In view of the relationship between these groups, Applicants maintain that examination of Groups II-XVIII along with elected Group I would not impose an undue burden on the Examiner. In particular, a search for art related to the subject matter of Group I would reveal art related to the subject matter of Groups II-XVIII and vice versa. Accordingly, to require the filing of a separate divisional application directed to Groups II-XVIII would result in the very same search for art being repeated. Such duplicate effort would be inefficient to the operation of the Patent and Trademark Office. Furthermore, it is likely that the same Examiner would be in charge of the divisional application, but since the divisional application would be examined at a later date, the Examiner would have to conduct a duplicate, redundant art search for the divisional application.

Moreover, as a result of the GATT legislation limiting the term of a patent to twenty years from its effective filing date, the delay in the examination of the non-elected claims likely would result in the patent term for these claims being unnecessarily shortened.

Therefore, since the outcome of the present restriction requirement would be to delay the examination of the claims of Groups II-XVIII, resulting in inefficiencies and unnecessary expenditures by Applicants, and since a single search can be performed (and has been performed) for all the subject matter defined by the claims in Groups I-XVIII without any significant burden on the Patent Office,

Applicants respectfully request reconsideration and withdrawal of the restriction requirement so that Groups I-XVIII will be examined on the merits together in the instant application.

Dated: June 17, 2004

Respectfully submitted,

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